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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,431	07/18/2003	Jay D. Kranzler	CYPR 100 CIP CON	4067
7278	7590	04/17/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/623,431

Applicant(s)

KRANZLER ET AL.

Examiner

Michel Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-49, 56-65 and 71-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-49, 56-65 and 71-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Action***

Claims 26-49, 56-65 and 71-93 are pending and examined.

Applicant has amended claims 26-28, 30-31, 34-36, 37-39, 42-46, 49, 56-59, 61-64 and 71-74 and provided arguments for the patentability of claims 26-49, 56-65 and 71-93 in the response filed 16 November 2005.

Applicant's arguments, see response, filed 16 November 2005, have been fully considered and are persuasive only to the extent that the rejection under 35 USC § 102 of claims 28, 58 and 63 with the recitation "wherein the SNRI has NMDA receptor antagonist properties" is withdrawn. Therefore, the rejections under 35 USC § 102 with respect to claims 26, 29, 32-33, 35, 39-41, 43, 47-48, 56, 60, 61, 65-66, 70-71, 73, 75 and 35 USC § 103 are maintained. Additionally, upon further consideration, new ground(s) of rejection are made.

The terminal disclaimer filed 16 November 2005 is acknowledge and to that end the Double Patenting rejection is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action as well as the text of all maintained rejections.

### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-49, 56-65 and 71-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate

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written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose or an applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice reduction to drawings or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. The above rejected claims recite, or depend upon a claim which recites a negative limitation such as for example the phrase "a compound that is not a neurotransmitter precursor" and "is not milnacipran" in claim 1. A negative limitation does not provide one of ordinary skill in the art with any description of what the Applicant claims as the invention. Therefore, with regard to claims 26-49, 56-65 and 71-93, the Applicant has not provide predictable operability of the invention to one of ordinary skill in the art.

***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-49, 56-65 and 71-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-49, 56-65 and 71-75 are of indeterminate scope. Defining a compound(s) by its (their) underlying functionality renders the scope of intended uses indeterminate since, the claim language may read on compounds not yet known or not yet understood. Moreover, determining whether a given compound agonizes or antagonizes one or more receptor sites involves much experimentation since a negative response from one patient does not necessarily mean the drug isn't useful, as no drug has 100% effectiveness. Thus, what success rate determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, paragraph two, is whether applicants have clearly defined their invention, not what may be discovered by future research as this type of claim language clearly requires. Therefore, a "NE[ $\geq$ ] $\geq$ 5-HT SNRI" and any limitation that is recited in the negative, such as those rejected above under 35 USC § 112 – 1<sup>st</sup> Paragraph are of indeterminate scope.

Claims 27-34, 36-42, 44-49, 57-60 and 71-75 recite the limitation of a compound of formula 1. There is insufficient antecedent basis for this limitation in the claim. For example, claim 26 recites the limitation that the compound is not milncaipran wherein such compound is included in the structure of formula 1 when n is 0, R1 and R2 are ethyl and R3 and R4 are H.

***Response to Arguments - 35 USC § 102***

Applicant's arguments filed 16 November 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a SNRI that has NMDA receptor antagonistic properties) are not recited in all of the rejected claim(s). With respect to claims 28, 58 and 63 for example which do recite such limitation, the WO 00/32178 reference contemplates SNRIs and milnacipran for example, having such properties would have been obvious to one of ordinary skill in the art. Therefore, as noted above, the rejection under 35 USC § 102 has been withdrawn with respect to claims 28, 58 and 63, but maintained otherwise.

***Response to Arguments - 35 USC § 103***

Applicant's arguments filed 16 November 2005 have been fully considered but they are not persuasive.

Again, Applicant argues the inherency issue of NMDA receptor antagonist properties in the cited reference. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a SNRI that has NMDA receptor antagonistic properties) are not recited in all of the rejected claim(s). With respect to claims 28, 58 and 63 for example which do recite such limitation, the WO 00/32178 reference contemplates SNRIs and milnacipran for example, having such properties would have



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been obvious to one of ordinary skill in the art. To that end, the structure of formula 1 includes milnacipran for example and therefore includes compounds which are SNRIs having NMDA receptor antagonistic properties.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11 April 2006

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